REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks is respectfully requested.

Claim amendments/Status

Claims 43-54 and 56-77 remain pending in the application. Claims 56-71 and 73 is/are withdrawn from consideration.

Rejections under 35 USC § 112

1) Claims 43-54, 72 and 74-77 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2) Claims 43-54, 72 and 74-77 are rejected under 35 USC 112, first paragraph, as based on a disclosure which is not enabling.

In connection with the indefinite issue it is asserted that 1) the six solenoid valves and the back-pressure regulator are not properly linked to the system and 2) the parts listed in the claims are not structurally linked to the "system." What is meant is not understood. The only reference to "system" is found in claim 77 and this has been removed in this response. What 'system' is the examiner referring? What is claimed is a "device."

Further, the claims recite the six solenoids as being connected with structure such as the water reservoir and the air compressor and the membrane module. The back pressure regulator is recited as being associated with at least one of the six solenoid valves for relieving back pressure in excess of a predetermined limit. Therefore, each of the elements are recited in connection with at least one other element and the claim format is therefore proper. It is pointed out that the purpose of the claims is not to explain the operation of the claimed structure merely to delimit the scope of protection.

In connection with the alleged enablement issue, the rejection asserts that the structural relationship between the six solenoid valves and the rest of the system:

> are [is] critical or essential to the practice of the invention because the amended claims and the applicants' arguments stress the importance of the six solenoids for patentability over the cited arts, but not included in the claim(s) is not enabled by the disclosure. (Emphasis added)

Syntactically, the rejection is not clear and seems to become even more unclear with the "for patentability over the cited arts, but not included in the claim(s) is not enabled by the disclosure", statement.

Nevertheless, is must be presumed that the rejection is taking issue with disclosure of the six solenoid valves. These are shown in Fig. 7 and repeatedly referred to throughout the specification. The combinations of the solenoids are referred to at least in the table on page 6; at page 10, lines 6-26; the table on page 14; page 15 lines 19-23; and page 17, lines 26-28. Taken as a whole, the specification explains the relevance of the six solenoid valves in a manner which would enable a person of skill in this particular art to make and use the invention, including the valves, without undue experimentation.

Without undue experimentation does not mean "no experimentation" or "little to no experimentation." The determination that "undue experimentation" needs to make and use the claimed invention and is not a single, simple factual determination. Rather, it is a conclusion reached by weighing a number of factual considerations. Indeed, the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm"n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

Rejections under 35 USC § 103

It is submitted that order to establish a *prima facie* case of obviousness, it is necessary

to show that the hypothetical person of ordinary skill would, without any knowledge of the claimed subject matter and without any inventive activity, be provided with disclosure of all of the claimed elements and then motivated to arrive at the claimed subject matter given the guidance of the cited references when each is fully considered as statutorily required. It is submitted that the Examiner has failed to meet these requirements in the following two rejections.

Further, the Applicants would like to traverse the position that the apparatus taught by the combination of the references applied in the following rejections "are capable of performing the function recited" in the claims. This kind of generalization, if proper, would allow combinations of references to applied without fully meeting the burden imposed by § 103.

1) Claims 43-54, 72 and 74-77 are rejected under 35 USC 103(a) as unpatentable over Daly et al. (US 6,120,688). This rejection is traversed.

Daly et al. discloses a method and apparatus for producing drinking water from impure water and more particularly, it relates to a portable apparatus and method for producing drinking water from impure water using micro-filtration unit and reverse osmosis unit which permits continued operation of the reverse osmosis unit during cleaning or back flushing the micro filtration unit to efficiently produce portable water.

The claimed invention differs from the cited prior art in the sense that the device can speedily remove more than 80% water and prevent degradation of temperature sensitive bioactive molecules from the aqueous plant extracts at ambient temperature. Moreover, Daly et al. does not teach or solve the technical problem of speedy removal of water from the aqueous extracts of plant without degradation of bioactive molecules. Therefore, Daly et al. exhibits a shortcoming which can be circumvented by this invention. The claimed device is suitable for effective concentration of herbal extracts, at the same time retaining all the important constituents and bioactive compounds in the concentrate. Besides, it has advantage for automatic washing of membranes and thus minimizes the problems of membrane bio fouling. This is not the mentioned in any of the prior art cited.

This rejection is traversed in that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). M.P.E.P. § 2143.03. Accord M.P.E.P. § 706.02(j).

More specifically, this rejection fails to indentify the Daly et al. reference as having at least a herbal extract solution container and air bleed valve. It further fails to indentify six solenoid valves are connected with the recited hardware. All that is asserted is that Daly et al. discloses that there are several solenoid valves. This is too vague for a *prima facie* case of obviousness to be established.

2) Claims 43-54, 72 and 74-77 are rejected under 35 USC 103(a) as being unpatentable over JP 05-201872 or Lawhon et al. (US 4,643,902) with evidence from Gobel et al (US 4,491,600) and/or Dorai et al. (US 5,434,315). This rejection is traversed.

JP 5-201872

Japanese patent Application 4-242403 by Kikuo et al. (hereinafter JP 5-201872) discloses a process for the concentration of vegetable crude drugs by RO process, especially using commercial cellulose acetate membranes. The process involves the pH adjustment of the drug solution between 3-9 using acid or alkaline solution.

The disclosed invention differs from JP 5-201872 as given below:

a) The disclosed invention use the indigenous polyamide thin composite membrane having NaCl rejection of 92-94%.

b) No pH adjustment is required for concentration of the aqueous extract.

c) The present application discloses not only the process of concentration but also device consisting of various components with the facility for recirculation of the RO retenate to achieve greater than 80% concentration.

d) The disclosed invention discloses the concentration of the solutions at the operating pressures of around 5-6 kg/cm2 in order to avoid pressure impact on the sensitive natural compounds. JP 5-201872 mentions that concentration of the extract has been carried

out at 1-60 kg/cm2 which is very broad range and can't be considered as RO process alone.

This being said, the rejection is traversed in that all that is advanced in connection with JP 5-201872 is that it discloses a system for concentrating herbal extracts using reverse osmosis membranes, with prefilter and associated pumps, valves, etc. It is advanced that JP 5-201872 teaches using reverse osmosis for concentrating the extract especially for extracts which have volatile components. Types of membranes including TFC are also taught. See pages 5 and 6 of the reference (of the English machine-translation).

The rejection acknowledges that is unclear if the reference specifically teaches recirculating the extract through the reverse osmosis system. However, to overcome this admitted shortcoming, the rejection advances that the reference clearly states at several places that the reverse osmosis concentration is "well known." This is hardly an in-depth analysis of the claimed elements and cannot be seen as establishing a *prima facie* case of obviousness. The combination of the recited elements is not rendered obvious and thus the rejection is untenable.

Lowhan et al.

Lowhan et al discloses a process for the concentration of fruit juice in two steps in which the first step is the removal of unwanted microorganisms by UF membrane process, and followed by RO concentration of the UF permeate using tubular RO membranes having > 99% rejection for NaCl. The disclosed invention differs from the cited US patent as given below:

a) This reference discloses a device wherein spiral module of thin film composite reverse osmosis membrane having NaCl rejection of 92-94% has been used for a single step concentration of aqueous herbal extracts at room temperature by recycling retenate continuously. Water passes through the membrane at considerably low operating pressure than the commercial RO membranes which have NaCl rejections of >99%, as reported in the Lowhan's patent.

b) The disclosed invention specifically teaches a simple device, as explained in the specification, for the concentration and purification of aqueous extracts at ambient temperature and moderate applied pressure whereas, the cited reference does not teach about the device

and the concentration aspects.

c) The disclosed invention uses spiral modules which have several advantages in terms of higher out put, lesser space and low energy consumption compared to the tubular membranes reported by the Lowhan et al.

The rejection based on Lowhan et al. is traversed in that all that is advanced is that Lawhon teaches using ultrafiltration and reverse osmosis membranes for concentrating various fruit and vegetable extracts as claimed in figures 1-3. The pre-filtration step to remove suspended matter is seen in column 4 lines 5-10. The ultrafiltration step provides OF concentrate, and permeate; the permeate containing flavor and aroma components, which is concentrated by reverse osmosis, and the reverse osmosis permeate being just solvent (or water) being discarded. Additional equipment such as tanks, solenoid valves, power supply, control panels, regulators, rubber 0-ring seals, etc., are inherent in the teaching of the reference.

However, again the question arises are all of the claimed elements disclosed as different from some nebulously broad overview which might or might not disclose what is actually claimed. The rejections appear to be nothing more than "close enough is good enough." Attention is called to the rather explicit recitation of elements in the claims under rejection.

It is submitted that it is necessary to show that all of the claimed elements are in fact disclosed in this reference and inasmuch Gobel et al. and/or Dorai et al. are merely relied upon for evidence, their teachings cannot combined to establish a *prima facie* case of obviousness. If their teachings are used, then the teachings of the documents taken as a whole becomes necessary.

Indeed, Dorai et al discloses a process for the fractionation of polyether glycols of different molecular weight distribution using ultrafiltration membranes of different molecular weight cut off values. It does not teach in any way the concentration of low molecular weight aqueous extracts. The claimed invention differs from the said patent in the following aspects.

a) The disclosed subject matter discloses a device wherein spiral module of reverse osmosis membrane having NaCl rejection of 92-94% has been used for the concentration of

aqueous herbal extracts at room temperature by recycling retenate continuously. Water and very low molecular weight solutes passes through the membrane at considerably low operating pressure than the commercial RO membranes which have NaCl rejections of >99%.

b) The UF membranes used in the Dorai et al. have very high molecular weight cut off values as compared to the solutes present in the herbal extract and are not useful for concentration of extracts. Whereas, the membranes of the disclosed invention have the capability to concentrate the low molecular weight extracts.

Gobel et al. on the other hand, discloses a process for the separation of high molecular weight unwanted enzymes and other materials from fruit juice by fractionation of using ultrafiltration membranes having specific molecular weight cut off value. In this process the low molecular weight vitamins, aroma, color materials, etc., passes through the high cut off value membrane whereas the high molecular weight proteins and enzymes are rejected. It does not teach in any way the concentration of low molecular weight aqueous extracts. The disclosed invention differs from the said patent in the following aspects.

a) The disclosed subject matter includes a device with spiral RO module for the concentration of aqueous herbal extracts at room temperature by recycling retenate continuously in a single step. It differs from the cited patent wherein two steps are involved: i) purification of the juice by UF membrane and ii) Concentration of UF permeate by freezing at low temperature and removing the ice crystals. This process requires more time and energy as it involves two steps of fractionation and low temperature freezing and crystal separation manually.

Conclusion

The cited references fail to disclose the recited combination of elements and are applied in a overall/general manner which is insufficiently specific to establish a prima face case of obviousness.

All objections and rejections having been addressed, it is respectfully submitted that the present application should be in condition for allowance and a Notice to that effect is earnestly solicited. The Examiner is invited to telephone the undersigned, Applicant's attorney of record,

to facilitate advancement of the present application.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 07-1337 and please credit any excess fees to such deposit account.

Respectfully submitted,
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